MEMORANDUM

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In Opposition to Connecticut SB 925
March 3, 2017

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes SB 925, legislation that would, among other things, require prescription drug manufacturers to provide advance notification of certain price increase and market entry prices as well as significant reporting by drug product. SB 925 will not help patients and could threaten access to needed prescription medications and the innovation of future treatments.

Discussions about the cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false - and ignores cost savings that medicines provide to the health care system overall. Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs. New medicines are making crucial contributions to medical advances, changing the direction of health care as we know it. This bill is likely to skew discussions of policy issues in ways that are systematically biased against innovation.

While this legislation singles out the biopharmaceutical industry, there are a variety of stakeholders involved in determining what consumers ultimately pay for a medicine, including insurers, pharmacy benefit managers, wholesalers, and government agencies like Medicaid. The important role that these entities play in setting drug prices and in drug coverage is overlooked by the requirements of this legislation. For example, pharmacy benefit managers (PBMs) and payers—which dictate the terms of coverage for medicines—use their control over which medicines patients can access as leverage to negotiate substantial rebates and discounts. **According to a 2017 Berkley Research Group (BRG) report, in 2015 branded manufacturers paid health plans and pharmacy benefit managers $57.7 billion in rebates and fees, paid $28 billion in Medicaid rebates, nearly $6 billion to close the Medicare Part D "donut hole", nearly $5 billion to Tricare and the Federal Supply Schedule in discounts, $3 billion for the ACA fee, and nearly $7 billion to support patient cost sharing assistance. Innovative companies paid more than $566 million in rebates for prescriptions filled through the Connecticut Medicaid program.** Further, the BRG report notes that brand biopharmaceutical companies realized just 39% of total gross drug spending, which is based off the list prices of medicines before rebates, discounts and fees are calculated. This is down from 41% in 2013 due to increases in the rebates and discounts paid to PBMs and payers. Increased rebates and discounts have largely offset increases in list prices and reflect the competitive market for brand medicines.

While shifting from fee-for-service to value-based design in the commercial market holds the promise of better patient outcomes and reduced costs over time, the mandate in SB 925 to unilaterally implement value-based design will burden the Department of Insurance greatly.

Any government role in regulating value-based insurance design and payment for health care services in the commercial market should be thoughtful, seeking input from all stakeholders, and should allow for an incremental approach. This proposal will sacrifice the thoughtful process that would be needed in making any approach to value-based design successful and serves as a mandate on both the Department of Insurance and health plans.

The Advance Notice Provisions Could be Harmful to the Market and to Future Innovation.

SB 925 would require manufacturers to provide advance notification of WAC price increases and new drug introduction to market. Providing notice of wholesale acquisition cost (WAC) increases or prices does not account for rebates, discounts, and other price concessions on these drugs and thus does not accurately reflect the true cost to an insurer.

According to the IMS Institute for Health Care Informatics, in 2015, brand prescription medicine invoice prices (~WAC prices) increased by 12.4 percent, but net prices only increased by 2.8 percent once rebates and discounts paid to insurers by biopharmaceutical manufacturers were removed. Patient premiums are only impacted by the net price, because that is the amount that insurers actually pay. Thus, the vast majority of the increases, balanced against the significant manufacturer discounts, when taken together, will not have any impact on a plan's overall costs. In addition, a manufacturer will not know at any one time, whether an increase of WAC will trigger these "annual aggregate" requirements. Further, such notification could result in voluminous reporting on price increases that will in no way assist in making thoughtful changes to formulary design or budgeting decisions. In practice, the pricing process is staggered.

Antitrust and other laws prevent competitors from "signaling" pricing decisions to competitors or engaging in conduct with competitors that could be viewed as collusion. Advance notification provisions will increase the risk of signaling, triggering potential legal and compliance issues. Advance notification of WAC price increases could also have the unintended consequence of increasing prices overall rather than helping to achieve cost savings, because such notification provides competitors the opportunity to *increase* prices with better certainty because they know in advance what their competitors are doing. This can create an artificial *price floor* rather than a price ceiling, with the result that the advance notice requirement could actually unwittingly lead to an overall increase in such costs to the detriment of insurer plans and their participants locally and, more importantly, *nationwide*.

Advance notification of WAC price increases creates financial incentives for secondary distributors to enter the pharmaceutical supply chain thus creating a "gray" market. Gray market distribution networks consist of a number of different companies – some doing business as pharmacies and some as distributors – that buy and resell medicines to each other before one of them finally sells the drugs to a hospital or other health care facility. As the medicines are sold from one secondary distributor to another, the possibility of counterfeit medicines augmenting the supply of legitimate medicines increases, thereby threatening patient safety. In the past, this type of purchasing has caused great difficulty for hospitals. During medicine shortages, hospitals are sometimes unable to buy medicines from their normal trading partners, usually one of the three large national "primary" distributors, AmerisourceBergen, Cardinal Health, or McKesson. At the same time, hospitals are deluged by sales solicitations from gray market companies offering to sell the shortage medicines for prices that are often hundreds of times higher than the prices they normally pay.

Requiring the notification of a 10% or $10,000 annual aggregate WAC price increase does not reflect a true understanding of the current practice of drug pricing and rebating in the country.

Such notification could result in voluminous reporting on price increases that will in no way assist in making thoughtful changes to formulary design or budgeting decisions. In practice, the process is staggered. Further, pharmaceutical manufacturers do not all take a WAC price increase on the same day. And, to complicate matters, a given company may not take a price increase on all of their drugs on the same day. Thus, there could literally be a price change for some product by some company on well over 100 days in a given year.

PBMs, insurers and government programs have protections in place that limit price increases.

Protections are in place through federal statute and in contracts with PBMs and insurers that limit the impact of any price increase on a payor for the duration of the contract. Through shrewd contract negotiations, payors are able to insulate their businesses from price increases. With respect to state Medicaid expenditures, companies must give the Medicaid program the "best price." Medicaid is further protected by a consumer price index (CPI) penalty that compounds with any price increase over CPI.

Proposals to Mandate Disclosure of Proprietary Information by Biopharmaceutical Companies Would Neither Benefit Patients Nor Decrease Healthcare Costs.

The biopharmaceutical industry is one of the most heavily regulated industries in the United States. Companies already report extensive information on costs, sales, clinical trials, and total research and development (R&D) expenditures. Neither HHS nor FDA is permitted to disclose this type of information, even if requested. Mandating disclosure of proprietary trade secrets would damage competition and increase costs. Further, providing the price disclosure anticipated in this legislation will not help decrease the financial burden of patient out-of-pocket expenses, increase consumers' understanding of their health care benefits, or reduce drug prices or overall health care costs. Importantly, proposals such

as these could result in limiting access to needed prescription medications and could stifle the innovation of future treatments.

SB 925 does not account for the value provided by innovative therapies nor the fact that medicines are *the only* part of the health care continuum that decrease over time as generics become available.

It is important to remember that these advances help control health care spending. Greater patient access to prescription medicines means fewer doctor visits and hospital stays and a decrease in costly medical procedures, all of which translate into lower health care costs overall. For example, in 2014, a new drug came to the market that provided a cure for more than 90% of patients with hepatitis-C, eliminating a lifetime of hospitalizations, debilitating symptoms, and treatments with harsh side effects and replacing it with a complete cure in just 12 weeks. Often, patients with hepatitis-C needed liver transplants, which could cost almost $500,000. Since 2014, several new treatment/cures have come to the market, further driving down the price of the medicine. Clearly, innovation and progress in the pharmaceutical industry means better outcomes and quality of life for patients and their families as well as reduced healthcare costs to patients and the system.

Further, medicines are the *only* part of the health care system where costs decrease over time. When brand name medicines face brand competition, or when medicines lose their patent protection and generic drugs become available, prices drop, often significantly. Today, nearly 90% of all medicines dispensed in the United States are generic and cost pennies on the dollar. One component of health insurance, however, is seeing significant increases. Health insurance and plan *administration costs are rising at more than twice the rate of drug spending.* Over the past five years, spending growth on prescription drugs averaged 2.2%, while growth in health plan administrative costs averaged 4.6%.

If the intent of SB 925 is to improve access and affordability to needed medicines, the language of the bill is misguided.

The intent of the legislation is misguided. If the intent is to help patients better understand drugs costs, this bill will in no way serves that educational purpose. The legislation does nothing to address how much consumers ultimately pay for a medicine; an amount determined by insurers not biopharmaceutical companies. Recent data shows that insurers are increasingly requiring patients to pay exorbitant out-of-pocket costs to access the medicines they need, far more than other health care services covered by an enrollee's health plan. This is contrary to the purpose of insurance—to spread the costs of health care utilization so that patients can access affordable needed care, including medicines.

Today, a patient pays only about 5% for out-of-pocket hospital costs but 20% or more for their medicines. Additionally, insurers are increasing utilization management techniques to aggressively restrict a patient's use of medicine. Currently, three major pharmacy benefit managers (PBMs) negotiate steep discounts on prescription drugs for approximately 75 percent of all prescriptions filled in the United States—Express Scripts alone covers 90 million Americans. Each time a PBM or other entity achieves a larger discount on a drug purchased in the commercial market than the federal minimum rebate of 23.1% of average manufacturer price (AMP), state Medicaid programs benefit immediately without having to do anything—because by federal law, states must receive the best price that any commercial entity receives for a drug. In addition, state Medicaid programs are insulated from prices that increase faster than inflation. Specifically, the Centers for Medicare and Medicaid Services charges an additional rebate called the "inflation penalty" any time the price percent of increase is greater than the percent increase of the Consumer Price Index-Urban (CPI-U). All of this happens automatically for the state.

Instead, this legislation seeks to require prescription manufacturers to disclose proprietary information and ultimately desires to determine whether the cost of a prescription drug is reasonable, which is the threat of price controls. However, any effort to implement a price control or to cap a drugs price would be vulnerable to a federal preemption challenge. Federal courts have stricken price controls before due to the impact on individual patent rights (see *PhRMA and BIO v. District of Columbia* (Fed Cir. 1997) which demonstrated that a price control undercut a company's ability to achieve the objectives of the federal patent law).

In closing, the biopharmaceutical industry is committed to working with Connecticut lawmakers, patients, doctors, and other health care stakeholders to pursue policies that promote innovation and help ensure consumers have access to needed medicines. However, SB 925 is not the way to accomplish this important goal and, therefore, PhRMA respectfully urges lawmakers to oppose this bill.